



Methodological Note - 2016

Accompanying document for the public Transparency
of Transfer of Value to Healthcare Professionals and
HealthCare Organizations

Takeda Farmacéutica España S,A,

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1. General introduction

Collaboration between industry and health professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives. Industry and health professionals collaborate in a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit in to the patient pathway. Bringing greater transparency to this, already well-regulated, vital relationship is about building strengthening the basis for collaboration in the future. Society has increasingly high expectations for transparency, none more so than in healthcare. Takeda, as a member of the European Federation of Pharmaceutical Industries Associations (“EFPIA”), want to ensure we meet those expectations going forward.

This methodological note is intended to anyone who wants to better understand the working assumptions used to generate Takeda Spain disclosure report and how the disclosed activities are defined within Takeda.

2. Scope of the disclosure

Several internal interpretations were required in order to properly identify what is reportable Transfer of values (ToV) under current year EFPIA guidelines (<http://transparency.efpia.eu/the-efpia-code-2>), and the Code of good practices for Pharmaceutical industry and Farmaindustria (<http://www.codigofarmaindustria.es/web.nsf/home.xsp>) .

We have summarized below our interpretation and working assumptions which we consistently applied while gathering data, what covered recipients’ means for us and the covered activities and expenses that are in scope.

2.1. Recipient scope

2.1.1. Healthcare Professionals (HCP): definition and scope

In the disclosure report, Takeda has taken into account the definition of HCPs as per the Spanish Code of good practices for Pharmaceutical industry and Farmaindustria with whom we may have transfer of values. The address of publication of the HCPs that are taken into account in the disclosure report is the primary practice address of the HCP.

2.1.2. Healthcare Organisations (HCO): definition and scope

In the disclosure report, Takeda has taken into account the definition of HCOs as per the Spanish Code of good practices for Pharmaceutical industry and Farmaindustria For instance, here type of HCOs with whom we may have transfer of values: *Associations, Hospital Federation, Hospital department, Care education centre, Clinic, Dental Clinic, Dispensary, Institution, Faculty, University, Academy school, Foundation, Grouping of pharmacies, Health institution*. The address of publication of the HCOs - that are taken into account - is the public address of the HCO.

2.1.3. Company owned by an HCP

If the company (HCO) is owned by one HCP, the transfer of value is reported against the individual HCP. If the company is owned by more than one HCP the transfer of value is reported as an HCO.

2.1.4. Clearly identifiable recipient

Takeda has put in place an internal process in order to ensure that transfer of values are allocated to the proper HCP or HCO, and to ensure that the disclosed information is accurate and complete (e.g. name, address, unique official ID whenever required, primary country of practice).

2.2.Medicinal scope

The report only refers to prescription only medicine and not over the counter products.

2.3 Activities scope

The activity definitions may vary amongst companies. Within Takeda, all our interactions with HealthCare Professionals are guided by TAKEDA internal Policies and Standard Operating Procedures that have been developed in alignment with local country laws and regulations and local industry requirements. We are providing you below with our Company definitions to ease our Disclosure report reading.

2.3.1 Donations and grants to HCO

All the transfer of values regarding a donation or a grant between Takeda and a HCO are included in the scope of the disclosure. This transfer of values could be for instance:

- i. Donations (monetary and non-monetary)
- ii. Charitable contributions (if the organization is classified as HCO in the country)
- iii. Grants, as following:
 - o Medical educational grants (e.g. support of the education of HCPs): they could be monetary in nature (e.g. IISRs, defined as unsolicited, independent research whether the investigator or the institution (academic, private or governmental) serves as the sponsor and Takeda provides support in the form of study drug and /or funding), and non-monetary (i.e. benefits in kind such as. anatomical models)
 - o Non-Medical educational grants (e.g. support healthcare institutions in improving infrastructure)

2.3.2 Contribution to costs of event

All the transfer of values regarding a contribution to costs of event between Takeda and a HCP (directly, or indirectly via a third party) or an HCO are included in the scope of the disclosure. These transfers of values could be for instance:

- i. A travel fee (*e.g. flight, train, taxi, car hire, tolls, mileage reimbursement, parking, visa or other official documents necessary for an HCP to secure travel arrangements, travel health insurance, etc.*)
- ii. An accommodation fee
- iii. A registration fee (*Fees paid for a HCP or a HCO, to allow HCPs to attend medical/educational events not organized by Takeda*)
- iv. A sponsorship agreement with an HCO or a third party appointed by an HCO to manage an event, for instance *Third Party scientific Conferences, Congresses or Exhibits; Sponsorships via Medical Societies; National Industry Organizations; Hospitals and Teaching Institutions; Scientific Organizations; Regional, National, International and Global Conferences; Local Hospitals; Medical Centres.*

Whenever an HCP being sponsored to a third party meeting had to cancel his/her participation, this has not been included in our report, nor is any cancellation fees.

Examples of activities that could be covered under “Sponsorship agreements” in the Takeda disclosure report: *Rental of booth, advertisement space (electronic, paper, etc.), satellite symposia at a scientific congress, scientific courses provided by a HCO, opportunities to promote our products (including non-promotional), meeting sponsorships (e.g. organisation support)*

2.3.3 Fees for Service and Consultancy

All the transfer of values regarding a fee for services and consultancy between Takeda and a HCP or a HCO are included in the scope of the disclosure. These transfer of values concerns for instance a meeting or event (promotional or non-promotional) where the HCP or the HCP working for an HCO is a speaker, a trainer, an advisor, and could be:

- i. Fees (e.g. fee for services such as preparation time, rehearsal time, travel time and time required for the activity)
- ii. Related expenses to consultancy (e.g. travel cost accommodation fee.)

Examples of fees that could be covered under “Fee for Services & Consultancy (HCPs and HCOs)” in the Takeda disclosure report: *Speaker fees for Speaker Programs and Roundtables; Ad Hoc Consulting/Advising Arrangements; Faculty for Speaker Training Programs or training of Takeda employees or external parties; Faculty for Advisory Board Meetings; Study participant for Market Research (only if no double-blinded research); Medical writing; Data analysis; Development of educational materials; Market survey (only if not double-blinded survey); Consultancy (e.g. protocol advise, market access, reimbursement, high technology assessment)*

2.3.4 Research & Development

Transfer of values related to a Research and Development (R&D) activity are included in the scope of the disclosure. These transfers of values include transfer of values to HCPs or HCOs related to the planning or conduct of:

- i. Non-clinical studies intended for submission to regulatory authorities (as defined in OECD Principles on Good Laboratory Practice)
- ii. Clinical trials (as defined in European Directive 2001/20/EC)
 - a. Any clinical trial in humans using an unapproved medicinal product;
 - b. Any clinical trial in humans using an approved medicinal product where it will be used for an unapproved indication or otherwise it will be prescribed outside the terms of its marketing authorisation, or where patients are prospectively assigned to different treatments, or where the protocol requires diagnostic or monitoring procedures which would not have been performed if the patient was not in the trial;
 - c. Any other clinical trial in humans for which clinical trial approval from the regulatory authorities would be needed if the trial were to be conducted in the EU in line with EC Directive 2001/20.
- iii. A prospective observational study where the patient is prescribed and treated with an approved medicinal product in accordance with the marketing authorisation and current practice and with the other requirements set out in section 15.01 of the EFPIA HCP Code.
- iv. Other type of activity:
 - d. Activities associated with planning the inclusion, design or timing of non-clinical studies, clinical trials and/or prospective observational studies within the context of a development plan for a medicine
 - e. Activities associated with planning of particular non-clinical studies, clinical trials or prospective observational studies.
 - f. Activities associated with conduct of particular non-clinical studies, clinical trials or prospective observational studies.

Examples of activities that could be covered under “R&D transfer of values” in the Takeda disclosure report: *Clinical trials: regional and/or global, local non-interventional studies*

The transfer of values realized indirectly via a Clinical Research Organisations (CRO), are also included in the R&D section of the disclosure report.

Transfer of values related to R&D are reported as an aggregate total figure, with the exception of transfer of values related to retrospective non-interventional studies, which shall comply with the provisions of Article 15 of the EFPIA HCP Code, which are disclosed under the name of the individual recipient.

2.4 Transfer of value in Cross border interactions

Cross border transfer of values is part of our disclosure report. The cross border activities are disclosed in the country of HCP recipient's primary practice address.

For instance, if Spanish HCP consultant is contracted by a foreign Takeda legal entity, Takeda will be disclosing the associated transfer(s) of value in the Spanish disclosure report, in line with the HCP primary practice address.

3 Privacy consent to the disclosure and aggregate amount

The HCP individual disclosure of the ToV provided to an HCP is covered by the local privacy regulation.

In Spain, the HCP should provide his/her privacy consent to allow the publication of the received Transfer of Value at individual level. If the individual privacy consent is not provided, Takeda will publish the relevant Transfer of Value as aggregate value including all HCPs who did not provide their privacy consent.

For the individual HCP disclosure, Takeda has decided to collect privacy consent for each ToV that the HCP then all the related Transfer of values are to be disclosed at an individual basis. If the HCP/HCO does not give his consent for at least one transfer of value, then all the transfer of values related to this are all disclosed at aggregate basis.

For instance, if a HCP is contracted for 5 individual activities throughout the year, and gives his consent for the first four of them and refuses to provide his consent for the last one, then all the related transfer of values will be disclosed in the aggregate section of the report.

For HCO, transfer of values will be disclosed at an individual basis, as the local privacy regulation only applies for individuals.

At any moment, a HCP has the right to withdraw his/its consent for a given transfer of values. If it occurs before the official disclosure then, all the transfer of values for this particular HCP will be disclosed with the on aggregate section of the report.

While respecting the local privacy legislation, Takeda has made the best efforts to obtain the privacy consents necessary to disclosure of transfer of values at the individual level. Takeda is retaining evidence of the request/obtainment / denial of Privacy consent.

4. Working assumptions

4.1 Date of Transfer of Value

Within Takeda, each activity with HCO and HCP is subject to a rigorous need assessment and internal approval process. Upon approval, Takeda moves to contracting which covers Transfer of Value and Disclosure request for consent, whenever relevant. Performance of service requested is tracked, so that payments can be made according to contract terms and conditions.

In our country, and in line with our local industry, we are using the date the service was delivered as recognition of transfer of value.

By date of service, we mean the date when the service was effectively delivered, for example when the HCP participated to an Advisory Board, this will be the date the Advisory Board effectively took place that will be used for collecting all associated transfer of values (e.g. fees for services, travel cost) and will be disclosed according, even if some reimbursements are effectively taking place at a later stage..

The cut-off rule we applied, is the following:

If the date of service has taken place between January 1st and December 31st 2016, the Transfer of Value is in scope for our 2016 disclosure report.

Takeda has a very limited use of multi-years contracts, mainly related to R&D activities. For the remaining multi-year contracts related to other activities, we have taken into consideration the <services delivered during a calendar year/payments made during a given calendar year> as inclusion criteria for that calendar year related disclosure report.

4.2 Currency

Takeda Farmacéutica España S.A. has adopted the Euro for the disclosure report, as it is - in the moment of the disclosure- the country official currency. In the case a Transfer of Value was made in another currency than the official one, the amount has been converted using Takeda Company Treasury exchange rates, that are monthly updated.

Example of Transfer of Value made in foreign currency, is when the HCP incurred travel costs in a foreign country where he/she is delivering the service which we reimbursed.

3.3 Taxes

Fees being paid are subject to taxes. The amounts captured in our report are gross amounts.

4.3.1. Value-Added Tax (VAT)

Expenses such as travel or accommodation are subject to VAT. The data captured and disclosed are excluding VAT.

5. Dispute resolution management

Takeda has implemented an internal process for Dispute Resolution Management in case for instance of general questions and disagreements with the data that has reported and/or requests to add or remove HCP/HCO privacy consent to disclose data.

If you have comments or questions about Takeda processing of your information, this Methodological Note, the content of the disclosure, or Takeda Privacy Policy, please contact the Compliance department

of Takeda Farmacéutica España, at email address “ES_transparencia@takeda.com” or the contact indicated in the Takeda web site (<http://www.takeda.es>).

Departamento de Compliance de Takeda Farmacéutica España en la dirección o con la persona de contacto que se indica en la página web de Takeda (<http://www.takeda.es>).